

PATENT COOPERATION TREATY
PCT
INTERNATIONAL SEARCH REPORT
(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 064016355354	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No. PCT/CA2004/002172	International filing date (<i>day/month/year</i>) 21 December 2004 (21-12-2004)	(Earliest) Priority date (<i>day/month/year</i>) 23 December 2003 (23-12-2003)
Applicant MOUNT SINAI HOSPITAL ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows :

METHODS FOR DETECTING MARKERS ASSOCIATED WITH ENDOMETRIAL DISEASE OR PHASE

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority for the purposes of search.
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments :

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. ☐ Claim Nos. :
because they relate to subject matter not required to be searched by this Authority, namely :
2. ☒ Claim Nos. : 40 (partial)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

that portion of claim 40 that is part of Invention No. I is so grouped on the basis of its dependency on markers of claim 29. However, claim 29 is directed to an imaging method that does not define specific markers.
3. ☐ Claim Nos. :
because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :
indicated on extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :
1-22, 28, 29, 38 (partial), 39, 40 (partial), 47(partial), 48, 49
Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2004/002172

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7): C12Q-1/68; C12Q-1/02; G01N-33/53, 33/574; A61K-45/00, 49/00; A61P-35/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(7): C12Q-1/68; C12Q-1/02; G01N-33/53, 33/574; A61K-45/00, 49/00; A61P-35/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

DELPHION, CPD, BIOSIS, CAPLUS, EMBASE, MEDLINE, STN REGISTRY; Keywords: endometrial (markers, cancer), polypeptide, nucleic, in vivo, imaging, PET, MRI, chaperonin 10, groES

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No(s).
X	WO98/10291 A1 (CENTER FOR CLINICAL & BASIC RESEARCH (DK)) 12 March 1998 - the entire document	1, 2, 5, 6, 8-10, 38 (partial), 47 (partial), 48, 49
Y		3, 4
A		7, 11-22, 28, 29, 39
X	WO99/63115 A2 (REPROGEN INC (US)) 9 December 1999 - the entire document	1, 2, 5, 6, 8-17, 22, 47 (partial), 48, 49
Y		3, 4
A		7, 18-21, 38 (partial), 39

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents :	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 April 2005 (11-04-2005)

Date of mailing of the international search report

11 May 2005 (11-05-2005)

Name and mailing address of the ISA/CA

Canadian Intellectual Property Office

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Gatineau, Quebec K1A 0C9

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2004/002172

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant	Relevant to claim No(s).
X	WO99/63116 A2 (REPROGEN INC (US)) 9 December 1999 - the entire document	1, 2, 5, 6, 8-17, 22, 47 (partial), 48, 49
Y		3, 4
A		7, 18-21, 38 (partial), 39
X	WO01/62959 A2 (PROCRA BIOSCIENCES INC (CA)) 30 August 2001 - the entire document	1, 2, 5, 6, 8-17, 22, 47 (partial), 48, 49
Y		3, 4
A		7, 18-21, 38 (partial), 39
X	WO01/92338 A1 (THE BRIGHAM AND WOMEN'S HOSPITAL, INC (US); THE OHIO STATE UNIVERSITY (US)) 6 December 2001 - the entire document	1-5, 7-9, 11, 18, 47 (partial), 48, 49
Y		28, 29
A		6, 10, 12-17, 19-21, 38 (partial), 39
X	SHAARAWY, M. and EL-SHARKAWY, S.A. Biomarkers of intrinsic and anti-angiogenic activity in patients with endometrial hyperplasia and endometrial cancer. Acta Oncologica, 2001, Vol. 40, No. 4, pages 513-518, ISSN 0284-186X.	1-6, 8, 9, 19, 21, 22
Y		28, 29
A		7, 10-18, 38 (partial), 39, 47 (partial), 48, 49
X	KLEIN, A.K. et al. Detection of circulating tumor cells by cytokeratin 20 in the blood of patients with endometrial carcinoma. Gynecologic Oncology, September 2000, Vol. 78, No. 3 (pt.1), pages 352-355, ISSN 0090-8258.	1-6, 8, 9, 11-18, 20, 22
Y		28, 29
A		7, 10, 38 (partial), 39, 47 (partial), 48, 49
Y	WO00/16805 A1 (DIADEXUS LLC (US)) 30 March 2000 - the entire document	28, 29
A		1-22, 38 (partial), 39, 47 (partial), 48, 49

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2004/002172

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO9810291 A1	12-03-1998	AU4127597 A	26-03-1998
		CA2265470 A1	12-03-1998
		EP0931262 A1	28-07-1999
		GB9618600D D0	16-10-1996
		GB9707132D D0	28-05-1997
		JP2001501300T T	30-01-2001
		US2003044795 A1	06-03-2003
WO9963115 A2	09-12-1999	AU765750 B2	25-09-2003
		AU4230499 A	20-12-1999
		CA2334117 A1	09-12-1999
		EP1076723 A2	21-02-2001
		JP2002517208T T	18-06-2002
		NZ508690 A	30-05-2003
		US6387629 B1	14-05-2002
		US2002187499 A1	12-12-2002
WO9963116 A2	09-12-1999	AU760613 B2	22-05-2003
		AU4230599 A	20-12-1999
		CA2299436 A1	09-12-1999
		EP1002136 A2	24-05-2000
		JP2002517209T T	18-06-2002
		US6753138 B1	22-06-2004
		US2004096884 A1	20-05-2004
WO0162959 A2	30-08-2001	AU3717801 A	03-09-2001
		BR0108685 A	30-12-2003
		CA2399259 A1	30-08-2001
		EP1290218 A2	12-03-2003
		JP2003531580T T	28-10-2003
		US6777182 B2	17-08-2004
WO0192338 A1	06-12-2001	US6649359 B2	18-11-2003
WO0016805 A1	30-03-2000	CA2343918 A1	30-03-2000
		EP1115426 A1	18-07-2001
		JP2002526055T T	20-08-2002

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continuation of Box No. III:

The International Search Authority found multiple groups of inventions in this international application, as follows:

I. Claims 1-22, 28, 29, 38 (partial), 39, 40 (partial), 47(partial), 48, 49:

Methods, kits and diagnostic compositions for detecting and *in vivo* imaging endometrial markers associated with an endometrial disease, particularly endometrial cancer.

II. Claims 23-25, 38 (partial), 39, 40 (partial), 47(partial):

Methods and kits for assessing efficacy of a test agent for inhibiting endometrial cancer.

III. Claims 26, 38 (partial), 39, 40 (partial), 47(partial):

Methods and kits for inhibiting endometrial cancer in a subject.

IV. Claims 27, 38 (partial), 39, 40 (partial), 47(partial):

Methods and kits for assessing the endometrial cancer cell carcinogenic potential of a test compound.

V. Claims 30-37, 47(partial):

Markers identified by differential expression in endometrial samples that distinguish an endometrial phase or disease; kits thereof. The claimed markers are considered to be a distinct invention in that the markers are unlinked to any of the other inventions by dependency thereto. Consequently, it is held that the claims are directed to compounds not limited to a specific use.

VI. Claims 41-45:

Methods and kits for determining uterine endometrial receptivity and probability of successful implantation, monitoring effects of ovarian stimulation on uterine endometrial receptivity.

VII. Claim 46, 47 (partial):

Method of contraception by interrupting presence of endometrial marker; kit therefor.